IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/840,143
Inventor(s)	:	Jayant Ekanth Khanolkar *et al.*
Filed	:	May 6, 2004
Art Unit	:	1615
Examiner	:	Jeffrey T. Palenik
Docket No.	:	9626
Confirmation No.	:	7415
Customer No.	:	27752
Title	:	Softgel Encapsulated Pharmaceutical Compositions Comprising Concentrated Active Ingredients

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
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This Brief is filed pursuant to the appeal from the decision communicated in the Office Action mailed on December 22, 2010.

A timely Notice of Appeal and Petition for Extension of Time were filed on May 20, 2011.

REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company of Cincinnati, Ohio.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals, interferences, or judicial proceedings.

STATUS OF CLAIMS

Claims 1-4, 6-12 and 14-17 are pending and have been rejected in the application.

Claims 1-4, 6-12 and 14-17 are appealed.

A complete copy of the appealed claims is set forth in the Claims Appendix attached herein.

STATUS OF AMENDMENTS

No Amendment after the Final action of December 22, 2010, was filed. The claims under consideration were presented in the Amendment of September 28, 2010. There are no longer any §112 matters at issue.

SUMMARY OF CLAIMED SUBJECT MATTER

As defined in independent Claim 1, the invention herein relates to pharmaceutical compositions. (Page 3, line 18.) The compositions comprise about 55% to about 90% of a pharmaceutical active (page 3, lines 1-2) together with from about 9% to about 39% of a solvent (page 3, lines 4-5), all encapsulated within a soft gelatin capsule (page 3, lines 5-6).

As explained at page 3, beginning line 11, soft gelatin capsules exhibit instability problems such as hydrolyzation, premature dissolution, seam widening, softening, sticking, etc., when used to encapsulate liquid pharmaceutical compositions (page 3, lines 10-11). The present invention employs from about 0.001% to about 1.00% (page 4, line 3) of a stabilization agent to help solve such problems. The listing of stabilizing agents recited at Claim 1(b) appears at page 6, lines 17-21.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether Claims 1-4, 6-12 and 15-17 are obvious under 35 U.S.C. 103(a) and unpatentable over the combined teachings of Dobrozsi *et al.* (US Pre-Grant Publication

No. 2003/013377) and White (WO 94/25008) in further view of Kennedy (*The Thinking Person's Guide to Perfect Health: Chelation*).

ARGUMENTS

The entire Appeal hinges on whether 103(c) can be used to remove the key Dobrozsi '377 document from the cited combination of documents applied against the claimed invention.

At the outset, it is noted that Dobrozsi published on June 19, 2003. The present Application has a priority date of May 6, 2004. Accordingly §102(b) is not an issue.

The controlling issue in this Appeal is whether the Examiner is correct and the Dobrozsi document is applicable with White and/or Kennedy as §103 art against the present invention *via* §102(a), or whether Appellants are correct and Dobrozsi is applicable under §103 only *via* 102(e) and, thus, is subject to 103(c).

It has already been made of record that the present application and Dobrozsi were, at the time the claimed invention was made, owned by, or subject to an obligation of assignment to, The Procter & Gamble Company. (Amendment after First Office Action, filed January 15, 2010, page 6.) Since the present application has a filing date after November 29, 1999, it is Appellants' contention that the provisions of 35 USC §103(c) come into effect as to all such commonly owned/assigned §103(e) documents.

In support of their position that §102(e), rather than §102(a), is the proper statutory section to be considered in the present instance, Appellants have argued to the Examiner that the mere fact that the publication date of '377 is before the effective filing date herein is obviated by the fact that '377 belongs to what the MPEP calls "a new category of prior art". [MPEP 706.02(a) **B**.] Such "new category" relates to art that, together with the present Application now being considered by the Board, were, at the time of the claimed invention was made, owned by, or subject to an obligation of assignment to, the same Assignee (here, The Procter & Gamble Company).

Of course, this exception to the usual rules regarding printed publications may vanish under §102(b), but only if the later Application is not filed before the one-year

anniversary of such publication. As noted above, this is not the case in the present circumstances, since the May 6, 2004, filing date herein is before the one-year anniversary of '377's publication date of June 19, 2003.

In short, Appellants have argued that this matter falls within the explanatory chart at MPEP 706.02(k) Example 4, as follows:

Example 4. Assumption: Employees A and B work for C, each with knowledge of the other's work, and with obligation to assign inventions to C while employed. Employee B's application, which is pending on or after December 10, 2004, is being examined.

SITUATIONS	RESULTS
1. A invents X and files application.	This is permissible.
2. B modifies X to XY after A's application is filed. B files evidence establishing that A and B were both under obligation to assign inventions to C at the time the invention XY was made.	Provisional 35 U.S.C. *103 rejection > of B's claims based on provisional prior art under 35 U.S.C. 102(e) (A's application) <cannot be made; provisional double patenting rejection is made; no 35 U.S.C. **>103 rejection based on prior art under 35 U.S.C. 102(f) or 102(g) <made.
3. B files a terminal disclaimer under 37 CFR 1.321(c).	The provisional double patenting rejection made in B's application would be obviated if all requirements of 37 CFR 1.321 are met.

In response to this argument, the Examiner has referred Appellants to MPEP 2132.01, which is entitled "Publications as 35 U.S.C. 102(a) Prior Art."

In reply, Appellants can only point out that the introductory paragraph to the cited MPEP section concludes with the sentence, "Note that when the reference is a U.S. patent published within the year prior to the application filing date, a 35 U.S.C. 102(e) rejection should be made."

Appellants submit that, were this not also the case for pre-grant US patent publication (as in the present instance), any organization with a large R&D group would

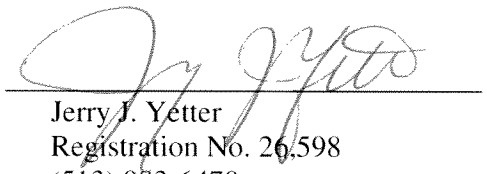
be loathe to allow any pre-grant publication of their US patent applications for fear of generating §102(a) art. Said another way, the safety features of §103(c) would be of little real use in the real R&D world.

In short, it is Appellants' position that, since Dobrozsi is not available as citable art, the rejection over the combination of Dobrozsi/White/Kennedy must fail, as a matter of logic and law.

SUMMARY

In view of the above, it is respectfully requested that all rejections under §103 over the cited combination of documents be reversed..

Respectfully submitted,
THE PROCTER & GAMBLE COMPANY



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CLAIMS APPENDIX

1. A pharmaceutical composition comprising:

(a) from about 55% to about 90% by weight of the composition of a suspended pharmaceutical active;

(b) from about 0.001% to about 1.00% by weight of a suspended stabilizing agent selected from the group consisting of phytic acid, disodium salts of ethylene diamine tetraacetic acid, calcium salts of ethylene diamine tetraacetic acid, tetrasodium ethylene diamine tetraacetic acid, sodium hexametaphosphate, di(hydroxyethyl)glycine, 8-hydroxyquinoline, and mixtures thereof; and

(c) from about 9% to about 39% by weight of a solvent;

wherein the composition is encapsulated within a soft gelatin capsule.

2. The composition of Claim 1 wherein the composition comprises from about 58% to about 80% by weight of the suspended pharmaceutical active.

3. The composition of Claim 2 wherein the suspended pharmaceutical active is selected from the group consisting of antitussives, antihistamines, decongestants, expectorants, mucolytics, analgesics, antipyretics, anti-inflammatory agents, local anesthetics, and mixtures thereof.

4. The composition of Claim 1 wherein the composition comprises from about 0.01% to about 1.00% by weight of the suspended stabilizing agent.

6. The composition of Claim 1wherein the suspended stabilizing agent is a disodium salt of ethylene diamine tetraacetic acid.

7. The composition of Claim 1 wherein the composition comprises from about 20% to about 39% by weight of the solvent.

8. The composition of Claim 7 wherein the solvent is selected from the group consisting of polyethylene glycols, polyvinylpyrrolidones, propylene glycols, glyceryl monolinoleates, glyceryl monooleates, C_8-C_{10} triglycerides, fractionated coconut oils, and mixtures thereof.

9. The composition of Claim 8 wherein the solvent is a polyethylene glycol solvent.

10. The composition of Claim 1 wherein the composition further comprises from about 0.1% to about 5% by weight of water.

11. A method of providing a stable soft gelatin capsule wherein the method comprises the steps of:

(a) formulating a pharmaceutical composition comprising:

i) from about 55% to about 90% by weight of the composition of a suspended pharmaceutical active;

ii) from about 0.001% to about 1.00% by weight of a suspended stabilizing agent selected from the group consisting of phytic acid, disodium salts of ethylene diamine tetraacetic acid, calcium salts of ethylene diamine tetraacetic acid, tetrasodium ethylene diamine tetraacetic acid, sodium hexametaphosphate, di(hydroxyethyl)glycine, 8-hydroxyquinoline, and mixtures thereof; and

iii) from about 9% to about 39% by weight of solvent; and

(b) encapsulating the composition of (a) within the soft gelatin capsule.

12. The method of Claim 11 wherein the suspended pharmaceutical active is selected from the group consisting of antitussives, antihistamines, decongestants, expectorants, mucolytics, analgesics, antipyretics, anti-inflammatory agents, local anesthetics, and mixtures thereof.

14. The method of Claim 11 wherein the suspended stabilizing agent is a disodium salt of ethylene diamine tetraacetic acid.

15. The method of Claim 11 wherein the solvent is selected from the group consisting of polyethylene glycols, polyvinylpyrrolidones, propylene glycols, , glyceryl monolinoleates, glyceryl monooleates, C_8-C_{10} triglycerides, fractionated coconut oils, and mixtures thereof.

16. The method of Claim 15 wherein the solvent is a polyethylene glycol solvent.

17. The method of Claim 11 wherein the pharmaceutical composition further comprises from about 0.1% to about 5% by weight of water.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.